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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,335	11/16/2005	Tim Cheeseright	DYOUNG0287US	8953
23908 7590 04/10/2008 RENNER OTTO BOISSELLE & SKLAR, LLP 1621 EUCLID AVENUE NINETEENTH FLOOR CLEVELAND, OH 44115				
EXAMINER				
SKOWRONEK, KARL HEINZ R				
ART UNIT		PAPER NUMBER		
1631				
MAIL DATE		DELIVERY MODE		
04/10/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/526,335

Applicant(s)

CHEESERIGHT ET AL.

Examiner

KARLHEINZ R. SKOWRONEK

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 19 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-856)
- Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Claim Status

Claims 1-13 and 16 are pending.

Claims 14 and 15 are cancelled.

Claims 1-13 and 16 are being examined.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following rejection is reiterated from the previous office action.

Claims 1-16 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1-16 are drawn to a process. A statutory process must include a step of a physical transformation, or produce a useful, concrete, and tangible result (State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998), AT&T Corp. v. Excel Communications Inc. (CAFC 50 USPQ2d 1447 (1999)). The instant claims do not result in a physical transformation, thus the Examiner must determine if the instant claims include a useful, concrete, and tangible result.

As noted in State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998) below, the statutory category of the claimed subject matter

is not relevant to a determination of whether the claimed subject matter produces a useful, concrete, and tangible result:

The question of whether a claim encompasses statutory subject matter should not focus on which of the four categories of subject matter a claim is directed to -- process, machine, manufacture, or composition of matter—but rather on the essential characteristics of the subject matter, in particular, its practical utility. Section 101 specifies that statutory subject matter must also satisfy the other "conditions and requirements" of Title 35, including novelty, nonobviousness, and adequacy of disclosure and notice. See *In re Warmerdam*, 33 F.3d 1354, 1359, 31 USPQ2d 1754, 1757-58 (Fed. Cir. 1994). For purpose of our analysis, as noted above, claim 1 is directed to a machine programmed with the Hub and Spoke software and admittedly produces a "useful, concrete, and tangible result." *Alleppat*, 33 F.3d at 1544, 31 USPQ2d at 1557. This renders it statutory subject matter, even if the useful result is expressed in numbers, such as price, profit, percentage, cost, or loss.

In determining if the claimed subject matter produces a useful, concrete, and tangible result, the Examiner must determine each standard individually. For a claim to be "useful," the claim must produce a result that is specific, and substantial. For a claim to be "concrete," the process must have a result that is reproducible. For a claim to be "tangible," the process must produce a real world result. Furthermore, the claim must be limited only to statutory embodiments.

Claims 1-16 do not require production of a tangible result in a form that is useful to the user of the process or apparatus. The claims are directed to a method of comparing molecules that involves using a calculated field of potentials for a first molecule and comparing the field of potentials for a second molecule relative to the first molecule by combining values of the potential fields to provide a score of similarity. The phrase "to provide a score" does not produce a tangible result in that it is not returned to the practitioner of the method. Under a broad but reasonable interpretation of the phrase "to provide a score", the phrase sets forth that the combining step is a scoring mechanism but stops short of producing a tangible result. A tangible result requires that the claim must set forth a practical application to produce a real-world result. This rejection could be overcome by amendment of the claims to recite that a result of the

process is outputted to a display, or to a user, or in a graphical format, or in a user readable format, or by including a result that is a physical transformation. The applicants are cautioned against introduction of new matter in an amendment.

Response to Arguments

Applicant's arguments filed 19 March 2008 have been fully considered but they are not persuasive. Applicant argues that the resultant score of the method is a tangible output. Applicant asserts that the score of the computer implemented method will reside in a computer buffer. However, a score residing a computer buffer is not tangible to the practitioner of the method and cannot be realized by the practitioner until the score is further acted upon. It is the further action that renders the score tangible. With respect to applicant's comparison of the instant claims to the claims of US PAT 6,996, 476, the comparison is inaccurate. The presented claim from the '476 patent employs an analysis step that involves independent component analysis (ICA). ICA is an inherently graphical method that, as indicated by the presented claim, presents data as clusters. The use of the graphical method ICA provides for a tangible result for the presented claim of '476 patent. ICA of the '476 patent is not comparable to the score produced by the instant claims. The rejection is maintained.

This rejection is newly applied.

Claim 13 is directed to an article of manufacture in the form of a computer readable recording medium. As guided by the specification (page 9, line 13-21) a computer readable medium may be a carrier signal. The specification teaches a t p. 9

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the computer readable medium that bears a set of instruction for carrying out the methods of the invention. At p. 9 line 19, the specification instructs a computer readable medium may also be a recording medium. In light of the guidance provided by the specification, a recording medium may also be a carrier signal. Claim 13 is rejected as being non-statutory because it has embodiments that are both statutory and non-statutory.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the

obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1, 2, 6, 7, 8, 10, 11, 12, 13, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ashworth (IDS, GB Patent Publication # 2,317,030, March 11th, 1998). This rejection is modified from the previous Office action.

The claims are drawn to a method of comparing molecules comprising:

- A) Providing field points of a first molecule,
- B) Determining, at the position of the field points of a first molecule, the field of a second molecule to obtain field sample values for a second molecule,
- C) Combining the information from (A) and (B) to obtain a score indicating similarity.

Ashworth discloses a method of determining field points for a molecule (abstract). Ashworth discloses the ability to obtain field points for a molecule in relation to the field points of another molecule (page 4, lines 21-26). Furthermore, Ashworth discloses that one can determine a similarity score by comparing field points of a first and second molecule (page 8, lines 4-7). Ashworth shows a method for screening molecules for similar activities based on field point comparisons. In the method, the field points for a first molecule are obtained (p. 4, line 29-30). Ashworth shows that a pharmacophore is determined which comprises a 3-dimensional array of field points defining a shape and volume of the field points derived from a plurality of molecules, reading on obtaining a set of sample field values (p. 4, line 22-26). In an embodiment,

Ashworth shows that the pharmacophore is tested to determine how well relates to activity. In that embodiment, field sample values (i.e. a pharmacophore) are determined from a plurality of molecules and the field points of each molecule of the plurality are compared or combined with the pharmacophore to determine a coulombic overlay energy value (p. 14, line 28-37). As defined by Ashworth at p. 8, line 4-12, coulombic overlay energy is an energy score that represents the similarity between two field point patterns and thus the similarity between the first and second molecules. The embodiment at p. 14, line 28-37 reads on the method as in claim 1 of the instant applications. While Ashworth discloses a method for obtaining field points of a molecule in relation to another molecule (as cited above), Ashworth does not explicitly show a method of comparing molecules. Rather, Ashworth shows a method screening molecules for an activity based on the similarity of the molecule's field points relative to a pharmacophore.

With respect to claim 2, Ashworth discloses that the information associated with field points includes the position and size and extent. Furthermore, Ashworth discloses the use of equations in Vinter et al. (IDS, Journal of Computer Aided Molecular Design, Vol. 9, Pages 297-307) for calculations (page 10, lines 7-11) which applicant's specification details represent a field definition formula (page 12, lines 7-10).

With respect to claim 6, as referenced above, Ashworth discloses the use of the equations of Vinter et al. for the comparisons. Applicant discloses the equation used for comparison by Vinter et al. (specification, page 6, line 4) where the equation is

taking the product of field point values (top line) which, as disclosed by Ashworth (as referenced above), consider size/extent and position.

With respect to claim 7, with the requirement for determining an aggregate score calculation, Ashworth discloses aggregate averaging (abstract, lines 10-11).

With respect to claims 8, and 10, they represent the limitations of claim 7 as applied in conjunction with claims 2 and 6, respectively. Since Ashworth discloses the limitations of claims 2 and 6 (as referenced above) and Ashworth is using an analogous method on the various molecules used to reach an aggregate value, Ashworth discloses the limitations of claims 8 and 10.

With respect to claim 11, since, as disclosed by Ashworth, the field size value is a value taken into account in defining the field point (as referenced above) and the field point values are energy values (measurement of energy extrema, for example, see Vinter et al., abstract), the field size values under consideration by Ashworth et al. represent energy values.

With respect to claim 12, Ashworth discloses the use of positive or negative maxima (abstract, line 4), wherein applicant's definition of minima is a negative maxima (specification, page 7, lines 18-19).

With respect to claims 13-16, Ashworth discloses a computer apparatus for carrying out the method (page 8, lines 19-23). Ashworth's disclosure of such an apparatus necessarily discloses a computer-interpretable medium with the method since the computer couldn't execute the method unless the computer had the method on a computer-interpretable medium.

Ashworth does not show the determination of a second molecule's field points relative to a first molecule.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made to modify Ashworth's method to determine the similarity score between sets of molecules by determining a second molecule's field points in relation to that of the first molecule. One of ordinary skill in the art would have been motivated to do so, because, as suggested by Ashworth, one would expect changes in the field of a molecule relative to another molecule (page 4, lines 5-8). Hence, by determining a molecule's field points relative to another molecule, one would have a more accurate representation of the expected field.

Response to Arguments

Applicant's arguments filed 19 March 2008 have been fully considered but they are not persuasive. Applicant argues that method does not involve the determination of a second molecule's field points in relation to that of the first molecule. The specification defines "field sample values" on p. 7 line 10-16, as the field of a second molecule at a first molecule's field point and thus field sample values are field points of the second molecule, though not necessarily field extremes. Based on the guidance provided by the definition of field sample values, the interpretation of the determining step of claim 1 determination of a second molecule's field points in relation to that of a first molecule accurately rephrases what is claimed. As indicated in the claim each field point has a position and a field size. In the combining step the field sample values, which are field points of the second molecule, are combined with the field points of the first molecule to

produce a score. Correspondingly, Ashworth shows a method for screening molecules for similar activities based on field point comparisons. In the method, the field points for a first molecule are obtained (p. 4, line 29-30). Ashworth shows that a pharmacophore is determined which comprises a 3-dimensional array of field points defining a shape and volume of the field points derived from a plurality of molecules, reading on obtaining a set of sample field values (p. 4, line 22-26). In an embodiment, Ashworth shows that the pharmacophore is tested to determine how well it relates to activity. In that embodiment, field sample values (i.e. a pharmacophore) are determined from a plurality of molecules and the field points of each molecule of the plurality are compared or combined with the pharmacophore to determine a coulombic overlay energy value (p. 14, line 28-37). As defined by Ashworth at p. 8, line 4-12, coulombic overlay energy is an energy score that represents the similarity between two field point patterns and thus the similarity between the first and second molecules. The embodiment at p. 14, line 28-37 reads on the method as in claim 1. Thus applicants argument and assertion that Ashworth does not disclose nor suggest "determining at the position of each of the field points of the first molecule the field of a second to obtain a set of field sample values" is not persuasive and the rejection is maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KARLHEINZ R. SKOWRONEK whose telephone

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number is (571)272-9047. The examiner can normally be reached on Mon-Fri 8:00am-5:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie A. Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

10 April 2008

/K. R. S./

Examiner, Art Unit 1631

/John S. Brusca/

Primary Examiner, Art Unit 1631